

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: WAVE 4 CASES LISTED IN EXHIBIT A	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**MEMORANDUM IN SUPPORT OF DEFENDANTS’
MOTION TO EXCLUDE SUZANNE PARISIAN, M.D. [WAVE 4]**

Defendants Ethicon, Inc., Ethicon LLC and Johnson & Johnson (“Ethicon”) move to exclude the testimony of Plaintiffs’ expert, Suzanne Parisian, M.D., in its entirety for the four cases identified in Exhibit A, relating to the TVT-Secur and Prolift + M devices only.¹ Ethicon incorporates the standard of review for the instant motion to exclude as articulated by the Court in its Memorandum Opinion and Orders in Waves 1 and 2.²

¹ Plaintiffs’ designation states that they recognize the Fourth Circuit’s affirmance of this Court’s exclusion of evidence of compliance with the 510(k) process and “reserve the right to designate” Dr. Parisian “[i]n the event of a contrary ruling.” Exh. B: Pls. General Expert Desig., p. 2. Ethicon understands this to mean that Dr. Parisian is not designated at all if no FDA evidence is admitted, even though this is potentially inconsistent with Dr. Parisian’s current disclaimer of reliance on FDA regulations. In addition, Ethicon notes that this “reservation of right to designate” in some instances puts Plaintiffs’ number of experts over the allotted five.

² *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4608165, at *2 (S.D.W. Va. Sept. 2, 2016) (Wave 1: hereinafter “Parisian Order”) (citing, inter alia, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1268790 (S.D.W. Va. Mar. 29, 2017) (Wave 2).

**INTRODUCTORY STATEMENT REGARDING COURT’S
PRIOR RULING ON DR. PARISIAN**

Dr. Suzanne Parisian is a non-practicing pathologist whom Plaintiffs have designated as a regulatory expert. Dr. Parisian is the subject of countless decisions from federal courts across the country. Whereas some courts have permitted her to testify, often on limited topics, federal district courts have described her opinions as “astonishing,” “egregious,”³ and “woefully deficient,”⁴ and have accordingly excluded her testimony.⁵ In the *Prempro* MDL, the United States Court of Appeals for the Eighth Circuit affirmed the District Court’s post-trial decision to

³ *In re Trasylol Prods. Liab. Litig.*, 709 F.Supp.2d 1323, 1342-1343, 1351 (S.D. Fla. 2010) (S.D. Fla. 2010).

⁴ *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp.2d 644, 666 (D. N.J. 2008) (scientific conclusions were “woefully deficient” and “nothing more than pure speculation”).

⁵ Scores of other federal district courts have likewise excluded all or much of Dr. Parisian’s proposed opinions. See *In re Mirena.*, 169 F. Supp.3d at 474-482; *Rheinfrank v. Abbott Labs.*, Case No. 1:13-cv-144-SJD (S.D. Ohio), Order Ruling on *Daubert* Motions (ECF No. 298), at 16-17, attached as Exh. C, *aff’d*, *Rheinfrank v. Abbott labs., Inc.*, No. 16-3347, 2017 WL 680349 (6th Cir. Feb. 21, 2017); *Bartoli v. Novartis Pharms. Corp.*, 2014 WL 1515970, *6 (M.D. Penn. Apr. 17, 2014); *Rowland v. Novartis Pharms. Corp.*, 9 F. Supp.2d 553, 563 (W.D. Pa. 2014); *Stambolian v. Novartis Pharms. Corp.*, 2013 WL 6345566, *9 (C.D. Cal. Dec. 6, 2013); *Mathews v. Novartis Pharms. Corp.*, 2013 WL 5780415, *24-25 (S.D. Ohio Oct. 25, 2013); *Taylor v. Novartis Pharms. Corp.*, 2013 WL 5118945, *7 (S.D. Fla. Apr. 22, 2013); *Pritchett v. I-Flow Corp.*, 2012 WL 1059948, *6 (D. Col. Mar. 28, 2012); *Miller v. Stryker Instr.*, 2012 WL 1718825, *11 (D. Ariz. Mar. 29, 2012); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 467 (E.D. N.Y. 2011); *Hogan v. Novartis Pharms. Corp.*, 2011 WL 1533467, *40 (E.D. N.Y. Apr. 24, 2011); *Kaufman v. Pfizer Pharms., Inc.*, 2011 WL 7659333, *10 (S.D. Fla. Aug. 4, 2011); *In Re Heparin Prod. Liab. Litig.*, 2011 WL 1059660, *8 (N.D. Ohio Mar. 21, 2011); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 468 (E.D. N.Y. 2011); *Lopez v. I-Flow Inc.*, 2011 WL 1897548, *11 (D. Ariz. Jan. 26, 2011); *In re Prempro Prods. Liab. Litig.*, 2010 WL 5663003, *2-3 (E.D. Ark. Sept. 16, 2010); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp.2d 164 (S.D. N.Y. 2009); *Reece v. Astrazeneca Pharms., L.P.*, 500 F. Supp.2d 736, 745-56 (S.D. Ohio 2007); *Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *4-5 (E.D. La. Mar. 30, 2000). Review of state court testimony by Dr. Parisian in a mesh proceeding likewise revealed hours’ worth of narrative testimony, much of which was about the FDA’s 510(k) clearance process—which this Court has excluded in prior mesh cases. Compare Pl. Resp., Wave I, ECF No. 2148, at Ex. 1 (attaching transcript from *Barba v. Boston Scientific*, C.A. No. N11c-08-050 (Del. Sup. Ct.)), with Parisian Order, 2016 WL 4608165, at *3-4.

strike Dr. Parisian's entire trial testimony because she refused to abide by the court's rulings that limited her testimony. *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009). The *Prempro* district court cautioned that Dr. Parisian's testimony "reveals 'how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis.'" *In re Prempro*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). In this MDL, Dr. Parisian has prepared reports on two Ethicon products: the Prolift +M and TVT-Secur (a/k/a TVT-S); both reports are the same as were produced in Wave 1. *See* Exh. D: Suzanne Parisian Expert Witness Report, MDL 2327, Jan. 30, 2016: Prolift +M ("PM Rep."); Exh. E: Suzanne Parisian Expert Witness Report, MDL 2327, Jan. 30, 2016: TVT-Secur ("TVT-S Rep.").⁶

For the reasons stated in the Court's Memorandum Opinion and Orders in Waves 1 and 2, and for the additional grounds explained below, Dr. Parisian's testimony should be excluded in its entirety. In so arguing, Ethicon is cognizant of the Court's admonition that the parties not overlook *Daubert*'s core considerations for assessing expert testimony. *Parisian Order*, 2016 WL 4608165 at *1. The Court has also repeatedly noted that counsel should not expect the Court will align with its previous rulings "when faced with a different record," "especially when an expert has issued new reports and given additional deposition testimony." *Id.* That is not the case with Dr. Parisian, however: to the contrary, the record is the same as in Wave 1 (and Waves 2 and 3), in that Dr. Parisian has not submitted any new report nor has she given any new deposition testimony.

Accordingly, absent any new materials for assessment of Dr. Parisian's qualifications and the reliability or relevance of her opinions, Ethicon believes it appropriate to refer here to the

⁶ *See also* Exh. F: Parisian 3/8/16 Prolift +M Dep. Tr. ("PM Dep.") (full transcript); Exh. G: Parisian 3/8/16 TVT-S Dep. Tr. ("TVT-S Dep. Tr.") (full transcript); Exh. H: Parisian 2/12/15 (Garcia) TVT-S Dep. Tr. ("Garcia Dep. Tr.") (full transcript).

existing record and the Court's prior ruling on Dr. Parisian, as set forth below. Ethicon nevertheless cites, in abbreviated fashion, to the record and supporting case law for its argument below, incorporating by reference its Motion to Exclude Dr. Parisian and Memorandum in Support and Reply briefs from Waves 1, 2 and 3. *See* ECF No. 2079 (Mot.), ECF No. 2080 (Mem. in Support), and ECF No. 2229 (Reply) [Wave 1]; ECF No. 2387 (Mot.), ECF No. 2388 (Mem. in Support), and ECF No. 2572 (Reply) [Wave 2]; ECF No. 2840 (Mot.), ECF No. 2842 (Mem. in Support), and ECF No. 3019 (Reply) [Wave 3].

ARGUMENT

First, Dr. Parisian is not qualified to offer any opinions on issues such as medical causation or other scientific topics (e.g., product development, design, risks, testing, manufacturing, studies, and the standard of care for treating physicians), and any opinion she would seek to offer on such topics is not reliable or relevant. *See, e.g.*, PM Dep. 57-62 (testimony demonstrating lack of relevant training or experience including clinical trials, studies, design, testing, and inspection, as well as lack of knowledge regarding the actual Prolift + M or TVT-S devices), 149 (testimony confirming that she has never seen any clinical data regarding laser cut mesh). She lacks the necessary qualifications and reliable methodology to offer any such testimony, as many other courts have found. Of particular note are the district court's rulings in *Rheinfrank v. Abbott Labs.*, Case No. 1:13-cv-144-SJD (S.D. Ohio), Order Ruling on *Daubert* Motions (ECF No. 298), at 16-17, attached as Exhibit C, which excluded Dr. Parisian from testifying about "matters outside the scope of her expertise," including her opinion that certain birth defect risks were "knowable" to Abbott; "she is not qualified to opine that certain risks of Depakote would have been known by 2003 had Abbott conducted research sooner or in a

different manner.” That decision was affirmed by the Sixth Circuit on February 21, 2017, where the Court stated:

Rheinfrank also challenges the limitation placed on her regulatory expert, Dr. Parisian, who was not permitted to testify “that as of 2003, Depakote was known to be the most teratogenic drug.” But this limitation also was reasonable and therefore not an abuse of discretion. The district court concluded that Parisian was not qualified to give that testimony because even though she had an extensive background as an FDA Medical Officer and is a medical doctor, she is “not a teratologist and does not have any specialized knowledge or experience in evaluating [antiepileptic drugs],” *id.* The court concluded that such a specific opinion as to the teratogenic effects of Depakote relative to other antiepileptic drugs therefore “falls outside the scope of her expertise,” limited as that is by her regulatory background with the FDA and as a physician without any specialized understanding or expertise in antiepileptic drugs. As Rheinfrank appears to concede, Parisian is no specialist in teratology and therefore has no more specialized or expert understanding of antiepileptic drugs than any other licensed physician. The court could therefore reasonably conclude that her opinion about the relative teratogenicity of Depakote exceeded her expertise.

Rheinfrank v. Abbott Labs., Inc., No. 16-3347, 2017 WL 680349, at *10 (6th Cir. Feb. 21, 2017).

Scores of other district court decisions are in accord,⁷ including *Jones v. Novartis Pharms. Corp.*, No. 2:13-cv-624, 2017 WL 372246, at *9-10 (N.D. Ala. Jan. 26, 2017), which ruled that “Dr. Parisian is not qualified and will not be permitted to testify regarding causation or “causal association;” studies conducted on other drugs, correlations between femur fracture and osteonecrosis of the jaw; Dr. Parisian’s expertise does not lie in reviewing medical literature or determining whether causal associations exist between products and clinically significant hazards, and she does not have the expertise to assess whether a causal association existed that

⁷ See, e.g., *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp.3d at 475-76; *In re Trasyolol Prods. Liab. Litig.*, 709 F. Supp.2d 1323, 1337 (S.D. Fla. 2010); *Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *4-5 (E.D. La. Mar. 30, 2000) (in case involving hernia mesh, excluding Dr. Parisian in case involving ventral adhesion repair where Dr. Parisian clearly stated at her deposition that she has never worked with that or any other kind of mesh, is not a surgeon, and has never performed any medical research); *Bartoli v. Novartis Pharms. Corp.*, 2014 WL 1515970, *6 (M.D. Penn. Apr. 17, 2014);

would impact Novartis’ alleged failure to warn—“[t]herefore, none of Dr. Parisian’s testimony as to the existence of either causation or causal association will be permitted in front of a trier of fact in this case.”

Here, Dr. Parisian stated in her reports and testified that she will *not* address these topics. *See* PM Rep. ¶14, 23; TVT-S Rep. ¶14, 23; *see also* PM Dep. Tr. 46-48. And in Wave 1, Plaintiffs—based on the same record—conceded that Dr. Parisian will not offer any opinions on scientific topics, which the Court recognized this and denied the issue as moot. *Parisian Order*, 2016 WL 4608165 at *2. Ethicon reiterates its request that the Court find Dr. Parisian unqualified and her opinions lacking sufficient reliability and relevance for the reasons stated in Waves 1, 2 and 3 and as summarized above. At a minimum, Ethicon requests that the Court adhere to its prior determination and, based on the same record, find this issue moot and preclude Dr. Parisian from offering any testimony on these issues.

Second, Dr. Parisian should be precluded from offering testimony about Ethicon’s intent, motive, state of mind or bad faith because she is not qualified to offer those opinions; she does not have a reliable basis for her opinions; and these opinions are irrelevant. *See, e.g.*, TVT-S Rep. Ops. 1, 2, 4, 5. This type of proposed expert testimony—beliefs about the manufacturer’s

knowledge, state of mind, and whether it acted reasonably—is impermissible, as many courts have found.⁸

Consistent with this authority, in Wave 1, this Court—based on the same record now before the Court for Dr. Parisian—ruled that Dr. Parisian may not testify on corporate state of mind or intent. *Parisian Order*, 2016 WL 4608165 at *4 (order on “recurring issues”). Ethicon respectfully requests that the Court issue the same ruling here.

Third, Dr. Parisian’s regulatory opinions are inadmissible because they are irrelevant; amount to legal conclusions; constitute impermissible “narrative” testimony lacking adequate analysis; and are inadmissible under Rule 403.

Dr. Parisian’s opinions are premised on her personal belief that Ethicon withheld information from the FDA or engaged in actions that misled the FDA. *See, e.g.*, TVT-S Rep. Opinions 1-8. These opinions are irrelevant: “whether Ethicon violated particular sections of the FDCA or failed to furnish information to the FDA are not facts in issue in this case under Federal Rule of Evidence 702.” *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (“alleged shortcomings in FDA procedures are not probative to a state law products liability claim”); *see also Fowler v. Boston Scientific*, Case No. 2:13-cv-03932, at 18 (S.D. W. Va. June 3, 2016). Further, any opinion that Ethicon submitted false and misleading information

⁸ *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *3 (S.D. W. Va. Apr. 28, 2015) (“As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury’s fact-finding function by allowing an expert to testify as to a party’s knowledge, state of mind, or whether a party acted reasonably.”); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013), *on reconsideration in part* (June 14, 2013) (“Bard’s knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.”) (internal citations omitted). *See also Rheinfrank, supra* at 17 (“Dr. Parisian will also not be permitted to testify as to the ‘knowledge, motivations, state of mind, or purposes’ of Abbott, its employees, the FDA, or FDA officials.”); *In re Mirena*, 169 F. Supp.3d at 479-80; *In re Trasylol*, 709 F. Supp.2d at 1338; *Lopez*, 2011 WL 1897548 at *11 (collecting cases).

to the FDA is preempted; is an irrelevant legal opinion; and is irrelevant to the jury's determination of liability.⁹

Dr. Parisian's regulatory opinions are also inadmissible as legal conclusions. *See, e.g.,* TVT-S Rep. Conclusion, ¶¶318-319. An expert may not offer "ultimate question" testimony that Ethicon's actions were inadequate: testimony containing legal conclusions impermissibly conveys a witness's unexpressed, and perhaps erroneous, legal standards to the jury.¹⁰

Further, Dr. Parisian's regulatory opinions constitute impermissible narrative or, as some courts have deemed her testimony, a "regurgitation of facts." *See, e.g., In re Mirena*, 169 F.Supp. 3d 396, 475-76 (S.D.N.Y. 2016). As the district court explained in *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp.2d 164 (S.D. N.Y. 2009) when excluding Dr. Parisian, "[a]n

⁹ The FDA is the only entity in a position to determine whether it has been misled. For this reason, the court in *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp.2d 1312, 1329-30 (S.D. Fla. 2010), held that evidence of what information was or was not given to the FDA is only relevant to a fraud on the FDA claim, which is preempted by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350-51 (2001).

¹⁰ *See, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006); *In Re Heparin Prod. Liab. Litig.*, 2011 WL 1059660, *8 (N.D. Ohio Mar. 21, 2011); *Pritchett v. I-Flow Corp.*, 2012 WL 1059948, *6 (D. Col. Mar. 28, 2012) (Dr. Parisian's "lengthy written report occasionally lapses into unadulterated legal conclusions which are not only beyond her purview, but which usurp the important functions of the judge and jury").

expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on record evidence.” *In re Fosamax*, 645 F. Supp.2d at 192.¹¹

Dr. Parisian’s reports here follow the same pattern. The voluminous references to internal documents are untethered to her opinions. These statements consist—at most—of a bullet-point/paragraph listing of FDA regulations. This testimony is not reliable, is not helpful to a jury, and is inadmissible as unduly confusing under Rule 403.

Ethicon thus requests that the Court enter an Order finding Dr. Parisian’s testimony inadmissible as irrelevant and otherwise inadmissible for the reasons stated above. At a minimum, Ethicon requests that the Court rule as it did in Wave 1, thus precluding Dr. Parisian’s regulatory opinions for the reasons stated in the *Parisian Order*.

¹¹ See, e.g., *Rheinfrank*, *supra* at 17; *In re Trasylol*, 709 F. Supp.2d at 1338 (finding that Dr. Parisian “does not tie [the regulatory facts] to the opinions that they are intended to support.”); *Kaufman v. Pfizer Pharms., Inc.*, 2011 WL 7659333, *10 (S.D. Fla. Aug. 4, 2011) (“[w]hile Dr. Parisian devotes several pages of her report to restating and analyzing FDA regulations, she does not apply any of these regulations . . . to her report.”); *Lopez*, 2011 WL 1897548 at *10 (“Dr. Parisian’s report is a labyrinth that the Court cannot navigate. . . . Dr. Parisian’s report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation. . . . This deficiency has also been noted by other courts in excluding such testimony from Dr. Parisian.”); *Miller v. Stryker Instr.*, 2012 WL 1718825, *11 (D. Ariz. Mar. 29, 2012) (excluding Dr. Parisian because “much of [her] report regurgitates facts that should be submitted directly to the jury” and where she provided “no analysis or explanation” of her conclusory assertions); *Pritchett*, 2012 WL 1059948 at *7 (D. Col. Mar. 28, 2012) (excluding portions of Dr. Parisian’s testimony “regurgitating factual information that is better presented through introduction of documents or non-expert testimony”); *In re Prempro Prods. Liab. Litig.*, 554 F.Supp.2d at 880, 886 (overturning punitive damages award based on Dr. Parisian’s testimony in part because she “did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony” and “did not provide analysis, opinion, or expertise.”). Review of state court testimony by Dr. Parisian in a mesh proceeding likewise revealed hours’ and hours’ worth of narrative testimony by Dr. Parisian, much of which was about the FDA’s 510(k) clearance process, issues which this Court has excluded in prior mesh cases. See Pl. Resp., Wave I, ECF No. 2148, at Ex. 1 (attaching transcript from *Barba v. Boston Scientific*, C.A. No. N11c-08-050 (Del. Sup. Ct.)).

Fourth, Dr. Parisian's warnings opinions on the Prolift +M and TVT-Secur's IFU and patient brochures are inadmissible because (a) she is not qualified to offer such opinions and (b) she does not employ a reliable methodology.

In addition to Dr. Parisian's lack of any experience with design, testing or any analysis of mesh, *see* Garcia Dep. Tr. 101-105, 116, she is not sufficiently qualified to opine on product warnings for the following reasons—none of which is singularly dispositive, yet viewed in total reveal her lack of pertinent qualifications. She has never practiced medicine in the fields of surgery, gynecology, urology, or urogynecology. *Id.* at 94-95. She has no experience treating women for SUI with surgical mesh, *id.* at 94, 99, and has never seen how a TVT-Secur is implanted, has never implanted one herself, and admits that she lacks the expertise to do so. *Id.* at 99, 114.

Dr. Parisian testified as to her lack of pertinent experience while at the FDA and her lack of education, training and experience regarding implantation or counseling of patients for the TVT-Secur. TVT-S Dep. Tr. 66-69, 102-105. She does not have any information about the patient experience, such as whether patients have had no complications—or experiences with the product being safe and effective. *Id.* 70:3-9. She also does not know the risks that were associated with the device. *Id.* 71, 93-101. Further, Dr. Parisian has no basis to reliably opine as to whether the IFU is adequate for the intended users—pelvic floor surgeons—which is the pertinent inquiry. *See, e.g., Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984)

(manufacturer had duty to warn of risks that “were not well known to the medical community”).¹²

Ethicon requests that the Court enter an Order finding Dr. Parisian’s opinions on product warnings inadmissible for the reasons articulated above. At a minimum, Ethicon requests that the Court order, as it did in Wave 1, that Plaintiffs have conceded “that Dr. Parisian will not offer expert testimony about whether the relevant IFUs are adequate.” *Parisian Order*, 2016 WL 4608165 at *3.

Fifth, Dr. Parisian should not be permitted to opine on foreign regulatory matters. Whereas the Court’s Wave 1 Order reserved ruling regarding foreign regulatory and international standards, *see Parisian Order*, 2016 WL 4608165 at *3-4, the Court has not yet determined whether Dr. Parisian—who professes only a “working familiarity” with international standards and nothing more—is qualified. Nor has the Court yet determined whether Dr. Parisian has employed a reliable methodology.

Dr. Parisian expects to testify on issues including “foreign data,” and she refers to foreign regulations in her report. *See, e.g.*, PM Rep. ¶¶18, 68, 110, 112, 137-138, 187-188, 203, 208-209. Dr. Parisian, however, is not qualified to offer expert testimony on foreign regulatory

¹² Dr. Parisian does not know if pelvic floor surgeons—the individuals to whom warnings run—believe the device is safe and effective. TVT-S Dep. Tr. at 70-71. Dr. Parisian has never spoken with a doctor who has implanted a TVT-S; she has never spoken to a pelvic floor surgeon about the TVT-S; and she has read only one deposition of an implanting physician (in *Garcia*). TVT-S Dep. Tr. at 71-72, 84. She did not review any professional education materials regarding TVT-S, *id.* 72-78, she has not conducted any survey or study of pelvic floor surgeons about the risks they would understand from reading the patient brochure, *id.* at 84-85, and she has not conducted any survey or study of pelvic floor surgeons to determine whether they ever read the IFU—or to determine what risks they understood from the IFU, or from their education, surgical training, or review of relevant medical literature. *Id.* at 104-105. She has no opinion whether pelvic floor surgeons implanting the TVT-Secur should read the medical literature, testifying: “Yeah, I don’t have an opinion about that. I mean, they’re responsible for their practice.” *Id.* at 105.

matters: again, she attests only to a “working familiarity” with “International standards and requirements”—hardly a basis to deem Dr. Parisian qualified as an expert to present this material to a jury. *E.g.*, PM Rep. ¶18. As the district court found in *In re Mirena*, when it prohibited her from testifying about foreign regulatory issues: “Dr. Parisian is admittedly not an expert in the laws of foreign jurisdictions, and therefore is not qualified to testify on those subjects.” *In re Mirena*, 169 F.Supp. 3d at 477. In addition, as here, “[t]here is no reason to believe that the regulatory framework of [other countries] is similar to the FDA’s system.” *Id.* (also finding that Dr. Parisian’s report and proposed testimony in this area “is a recitation and reports and regulatory actions, with little or no analysis, which is not proper expert testimony” and ruling that “she may neither summarize foreign regulatory history nor imply that an action required abroad was necessarily required in the U.S.”). Accordingly, any opinions by Dr. Parisian on foreign regulatory issues should be excluded.

Sixth, Dr. Parisian should not be permitted to opine as to any product as to which she has not prepared an expert report. As noted above, the only products for which Dr. Parisian has prepared an expert report are the TVT-S and the Prolift + M. Thus, to the extent the cases identified in Exhibit A involve other products,¹³ Dr. Parisian must be precluded from offering any opinions.

¹³ See, e.g., Ex. A: *Shelby Anders v. Ethicon, Inc., et al.*, Case No. 2:12-cv-05168 (also asserting claims involving Proflit); *Candace Strauss, et al v. Ethicon, Inc., et al.*, Case No. 2:12-cv-05280 (also asserting claims involving Prosima and TVT Abbrevio).

CONCLUSION

For these reasons, Ethicon's motion to exclude Suzanne Parisian, M.D., should be granted and Dr. Parisian's testimony should be excluded in its entirety. Ethicon prays for all other relief to which it is entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones